

REMARKS

Claims 26-31 and 44-62, and new claims 63-91 are presented for consideration by the Examiner. Some of the claims have been amended in response to the rejections and remarks in the Office Action mailed February 26, 2003, and every ground of rejection has been addressed. The amendments are made without prejudice to any future submission of the original claims in a subsequent application.

1. OBJECTIONS TO DISCLOSURE ARE TREATED

Regarding the objection to the disclosure, in an attempt to streamline prosecution, Applicants have reinstated the original language in the specification, without prejudice to any future submission of the amended description in another application. Accordingly, the objection has been overcome by amendment consistent with the suggestions and remarks in the Office Action.

Applicants note that the claims in the present application are not limited to a particular type of material, such that a variety of any materials suitable to the operation of the invention is covered. The claims therefore cannot be avoided by others simply by a selection of materials. The claims cover a spacing implant having the recited elements of the claims and their equivalents,

whether constructed from metal, titanium, ceramic, bone, or any other biologically compatible material, since neither the invention nor the claims contain required limitations to specific material type or material category.

2. REJECTIONS OF CLAIMS UNDER 35 U.S.C. §§ 102 AND 103 ARE TREATED

Claims 26-28, 30 and 31 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,720,748 to Kuslich et al. (Kuslich). Claim 29 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kuslich. Claims 26, 27, 30, and 44-62 were rejected under 35 U.S.C. §102(b) as being anticipated by German Patent No. DE 299 01 611 to Aesculap (Aesculap). Claims 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Aesculap.

Regarding the rejection of the claims under 35 U.S.C. §§ 102 and 103, applicants' counsel has carefully studied the reasoning for the rejection provided in the Office Action, together with the two (2) prior art references relied upon. Applicants respectfully submit in good faith that certain rejected aspects of the invention are unanticipated, nonobvious and allowable. Additional limitations have been incorporated into the independent claims, without prejudice to any future submission of the original claims

in another application, which are believed to render said claims allowable.

Regarding claim 26, subject matter has been added to the claim, including "wherein said sheath member is confined to a size about the rod member sufficient to prevent the spacing member from entering the sheath member, and such that an end of the sheath member abuts the first end of the spacing member when the rod member is attached to the first end of the spacing member, to provide stability for positioning the spacing member." This subject matter added to claim 26 is supported in the disclosure, inter alia, on page 19, line 21 to page 20, line 5, and FIGS. 6-7, and is therefore not new matter.

The Kuslich and Aesculap references both disclose a sheath member that is sized so large with respect to the spacing member that the spacing member fits inside the sheath member. The sheath members disclosed by Kuslich and Aesculap are used as guide members on the outside of the spacing member. Accordingly, the sheath members do not abut the end of the spacing member to provide support as is now required in claim 26.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdeqall Bros. V.

Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since neither the Kuslich nor the Aesculap references disclose all the subject matter of claim 26, those references do not anticipate claim 26. Moreover, the combination of features of claim 26 are not taught or suggested by any of the prior art of record. Applicant's counsel has made a particular study of the other prior art of record, including U.S. Patent No. 5,306,308 to Gross et al., U.S. Patent No. 5,888,222 to Coates et al., U.S. Patent No. 5,741,253 to Michelson, U.S. Patent No. 5,776,199 to Michelson, U.S. Patent No. 6,143,032 to Schafer, and French Patent No. 2,736,537 to Thierry, in arriving at claim language sufficient to render claim 26 allowable over all of said prior art of record. Accordingly, claim 26 is believed to be allowable.

Defendant claims 27-29, 63 and 64 depend from claim 26 or a claim depending from claim 26, and are therefore believed to be allowable for at least the reasons given in support of claim 26.

Regarding claim 30, subject matter has been added to the claim including "said spacing member comprising an external, concavo-convex contour with respect to one dimension of said spacing member, said spacing member further comprising a length between a first end and a second end, and a width, said length having a

greater dimension than said width." This subject matter is supported in the disclosure, inter alia, on page 14, line 10 to page 15, line 7, and FIGS. 1-2, and is therefore not new matter.

The Kuslich reference does not disclose a spacing member having an external, concavo-convex contour. Moreover, the Kuslich and Aesculap references do not disclose "stabilizing means for removably contacting the spacing member along a contact line that surrounds the first area of attachment." As discussed above, the sheath members in both the Kuslich and Aesculap references are configured to receive the spacing members within the sheath. Accordingly, contact between the sheaths and the spacing members takes place over an area of the spacing members and not at a contact line. Moreover, space must necessarily be present between the spacing member and at least a part of the sheath so that the spacing members may fit within the sheaths and be moved into position (note the space 12 in FIG. 3 of the Aesculap reference, for example). Accordingly, contact between the spacing members and sheaths of the Kuslich and Aesculap devices does not surround the area of attachment.

Since the Kuslich and Aesculap references do not disclose all of the subject matter of claim 30, those references fail to anticipate claim 30. Moreover, a rejection for obviousness can

only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988). None of the prior art references of record provides a teaching, suggestion, or motivation to combine all of the features of claims 30. Applicant's counsel has made a particular study of the other prior art of record, including U.S. Patent No. 5,306,308 to Gross et al., U.S. Patent No. 5,888,222 to Coates et al., U.S. Patent No. 5,741,253 to Michelson, U.S. Patent No. 5,776,199 to Michelson, U.S. Patent No. 6,143,032 to Schafer, and French Patent No. 2,736,537 to Thierry, in arriving at claim language sufficient to render claim 30 allowable over all of said prior art of record. Accordingly, claim 30 is believed to be allowable.

Claim 31 depends from claim 30 and is believed to be allowable for at least the reasons given in support of claim 30.

Regarding claim 44, subject matter has been added to the claim including "an upper surface having a plurality of spaced apart elongate recesses formed therein." This subject matter is supported in the disclosure, inter alia, on page 15, lines 8-10,

and FIGS. 1-2, and is therefore not new matter. The Aesculap reference does not disclose, teach or suggest elongate recesses as required by claim 44. Moreover, the Aesculap reference does not disclose, teach or suggest a spacing member that is non-porous as required by claim 44. Applicant's counsel has made a particular study of the other prior art of record, including U.S. Patent No. 5,306,308 to Gross et al., U.S. Patent No. 5,888,222 to Coates et al., U.S. Patent No. 5,741,253 to Michelson, U.S. Patent No. 5,776,199 to Michelson, U.S. Patent No. 6,143,032 to Schafer, and French Patent No. 2,736,537 to Thierry, in arriving at claim language sufficient to render claim 44 allowable over all of said prior art of record. Accordingly, claim 44 is believed to be allowable.

Dependant claims 45-53 depend from claim 44 or a claim depending from claim 44, and are therefore believed to be allowable for at least the reasons given in support of claim 44.

Regarding claim 54, a combination of features are required including "said second end comprises a taper such that a thickness of said second end is less than a thickness of said first end." This subject matter is not disclosed, taught or suggested by the Aesculap reference. Moreover, the Aesculap reference teaches away from this subject matter. The Aesculap reference discloses guide

bodies 5 that may be spread apart by gripping parts 6 to increase the distance between vertebral bodies (see paragraph 51). Accordingly, the Aesculap reference teaches spreading the vertebral bodies further apart so that the spacing member can fit between the vertebral bodies, rather than providing a taper on the second end to facilitate insertion of the spacing member between vertebral bodies that are close together. It is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Applicant's counsel has made a particular study of the other prior art of record, including U.S. Patent No. 5,306,308 to Gross et al., U.S. Patent No. 5,888,222 to Coates et al., U.S. Patent No. 5,741,253 to Michelson, U.S. Patent No. 5,776,199 to Michelson, U.S. Patent No. 6,143,032 to Schafer, and French Patent No. 2,736,537 to Thierry, in arriving at claim language sufficient to render claim 54 allowable over all of said prior art of record. Accordingly, claim 54 is believed to be allowable.

Dependant claims 55-62 and 72 depend from claim 54 or a claim depending from claim 54, and are therefore believed to be allowable for at least the reasons given in support of claim 54.

Regarding new claim 65, claim 65 has similar subject matter as claim 26, with the addition of the spacing member having a cashew

shape. This subject matter is supported in the disclosure, inter alia, on page 12, line 21, and is therefore not new matter. Claim 65 is believed to be allowable for at least the reasons given in support of claim 26.

Regarding new claim 66, claim 66 has similar subject matter as claim 26, except that the positioning means has been replaced with a sheath member, a rod member slidably insertable into the sheath member, and a threaded portion on the rod member. This subject matter is supported in the disclosure, inter alia, claim 26 and page 22, lines 1-14, and is therefore not new matter. Claim 66 is believed to be allowable for at least the reasons given in support of claim 26.

Regarding new claim 67, claim 67 has similar subject matter as claim 30, with the addition of the spacing member having a cashew shape. This subject matter is supported in the disclosure, inter alia, on page 12, line 21, and is therefore not new matter. Claim 67 is believed to be allowable for at least the reasons given in support of claim 30.

Regarding new claim 68, claim 68 has similar subject matter as claim 44, with the addition of the spacing member having a cashew shape. This subject matter is supported in the disclosure, inter alia, on page 12, line 21, and is therefore not new matter. Claim

68 is believed to be allowable for at least the reasons given in support of claim 44.

Regarding new claim 69, claim 69 has similar subject matter as claim 44 except that the positioning means has been replaced with a sheath member, a rod member slidably insertable into the sheath member, and a threaded portion on the rod member. This subject matter is supported in the disclosure, inter alia, claim 44 and page 22, lines 1-14, and is therefore not new matter. Claim 69 is believed to be allowable for at least the reasons given in support of claim 44.

Regarding new claim 70, claim 70 has similar subject matter as claim 54, with the addition of subject matter wherein said taper operates to reduce a thickness of said second end with respect to said first end without reducing a width of said second. This subject matter is supported in the disclosure, inter alia, FIGS. 1-3, and is therefore not new matter. Claim 70 is believed to be allowable for at least the reasons given in support of claim 54.

Regarding new claim 71, claim 71 has similar subject matter as claim 54 except that the positioning means has been replaced with a rod member. This subject matter is supported in the disclosure, inter alia, claim 54 and page 22, lines 1-14, and is therefore not

new matter. Claim 71 is believed to be allowable for at least the reasons given in support of claim 54.

Regarding new claim 73, claim 73 has similar subject matter as claim 26 with the addition of subject matter including:

wherein said sheath member is sized to abut the first end of the spacing member and contactably circumscribe the opening;

wherein said sheath member is movable with respect to said rod in a direction away from said spacing member when said rod is attached to said spacing member; and

wherein said sheath member contacts said spacing member in a non-interference fit such that said sheath member can rotate with respect to said spacing member.

This subject matter is supported in the disclosure, inter alia, claim 26, FIGS. 7-8, and page 19, line 21 to page 20, line 5, and is therefore not new matter. Claim 73 is believed to be allowable for at least the reasons given in support of claim 26.

New dependent claims 74 to 77 depend from claim 73 and are believed to be allowable for at least the reasons given in support of claim 73.

Regarding claims 78-91, these claims have incorporated the bulk of the subject matter from claim 1 of U.S. Patent No. 6,579,318 (the present application is a division of the application

which resulted in U.S. Patent No. 6,579,318). Claims 78, 80, 82, 84, 86, 88, and 90 also include positioning means for enabling a surgeon to adjust a position of the spacing member when said spacing member resides between adjacent intervertebral bodies. Claims 79, 81, 83, 85, 87, 89, and 91 also include a rod member for enabling a surgeon to adjust a position of the spacing member when said spacing member resides between adjacent intervertebral bodies. This subject matter is supported in the disclosure, inter alia, page 22, lines 1-14, and is therefore not new matter.

Each of the claims 78-91 have removed some subject as compared to claim 1 of U.S. Patent No. 6,579,318. Claims 78 and 79 do not include a male corner line. Claims 80 and 81 do not require the spacing member to be non-porous. Claims 82 and 83 do not require the spacing member to be solid. Claims 84 and 85 do not require the spacing member to have a cashew shape. Claims 86 and 87 do not require the spacing member to have a uniform width. Claims 88 and 89 do not require the spacing member to be made of a rigid, non-resilient material. Claims 90 and 91 do not require the spacing member to have a smooth surface on the taper. The features required for the spacing member in each of claims 78-91, in combination with either the positioning means or rod member depending on the claim, are believed do define over the prior art

of record such that claims 78-91 are all believed to be allowable.

3. CONCLUSION AND AUTHORIZATION OF DEPOSIT ACCOUNT

In view of the foregoing, applicants believe that claims 26-31 and 44-91 are all allowable and the same is respectfully requested. If any impediment to the allowance of these claims remains after entry of this Amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to initiate the same.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 50-0836.

DATED this 26 day of August, 2003.

Respectfully submitted,



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